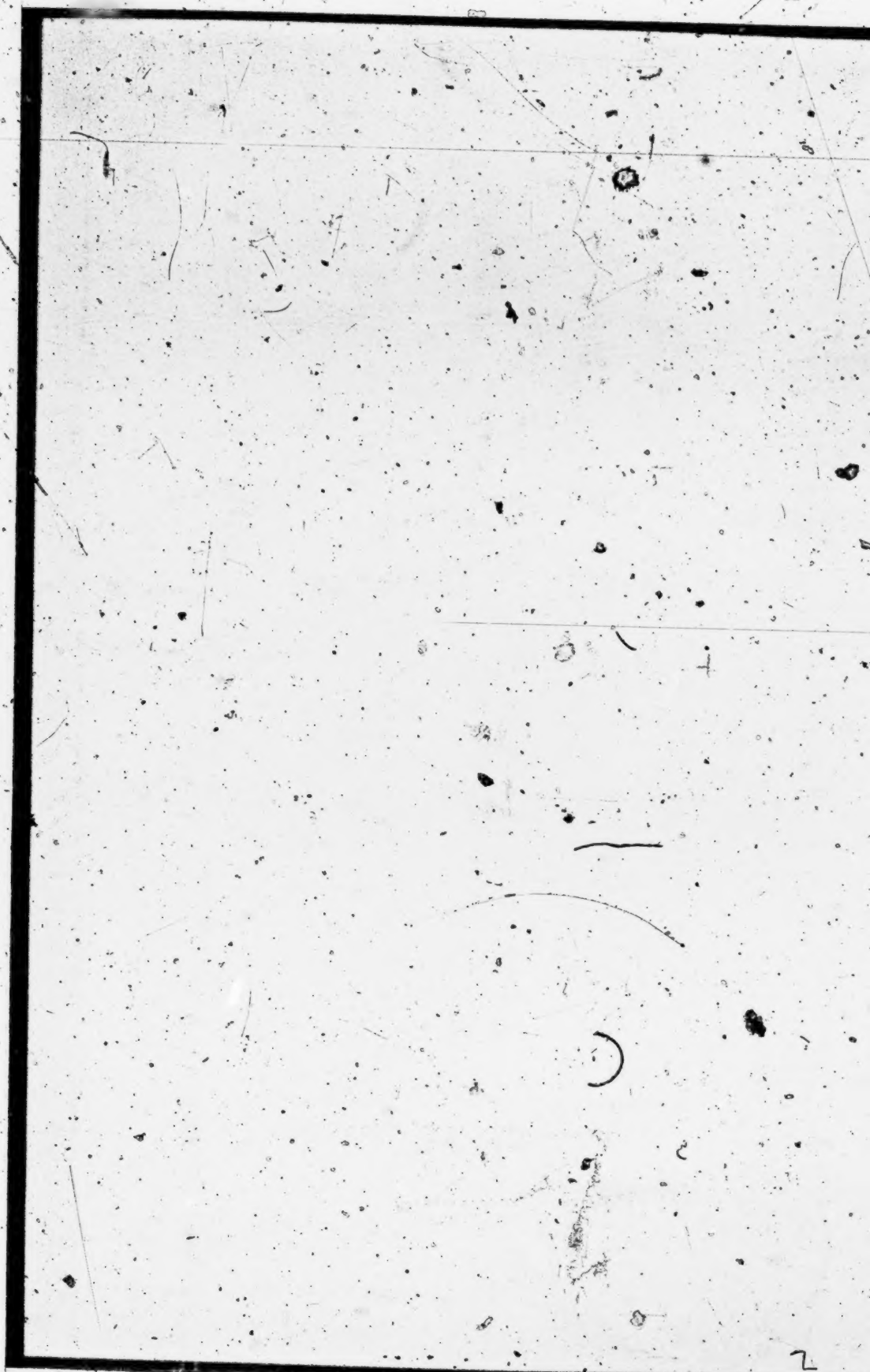


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UNITED STATES OF AMERICA,
*Petitioner,*

v.

AN ARTICLE OF DRUG * * * BACTO-UNIDISK * * *

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## PETITION OF CLAIMANT DIFCO LABORATORIES, INC. FOR REHEARING OF ORDER GRANTING PETITION FOR WRIT OF CERTIORARI

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## PETITION OF CLAIMANT DIFCO LABORATORIES, INC. FOR REHEARING OF ORDER GRANTING PETITION FOR WRIT OF CERTIORARI

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Respondent petitions this Court for rehearing of its order of October 21, 1968 granting the petition of the Government for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit herein, and, upon such rehearing, for denial of the writ.

### REASONS FOR GRANTING REHEARING AND DENYING THE WRIT

Since the Brief of Claimant Difco Laboratories in Opposition was filed in the instant Bacto-Unidisk case this Court, on October 14, 1968, denied the petition for a writ of certiorari in *AMP Incorporated* v. *Cohen*, No. 86, this term. Following the granting of the petition for a writ in the instant case, petitioner in *AMP* filed a Petition for Rehearing of the order denying its petition, stat-

ing in part as grounds therefor that this Court in the case at bar will be deciding the same issues as presented in *AMP*. On the other hand, the Government in its Brief in Opposition to the *AMP* petition had stated that the decision of the Court of Appeals for the Sixth Circuit in the instant case was not in conflict with the decision of the Appellate Court in *AMP* and that "whether or not the Sixth Circuit decision is correct, the case differs from the present one both factually and legally" (Brief in Opposition, 8-9). We agree with that statement of the Government. The Government, nevertheless, in its petition for a writ of certiorari in the instant case, contended that the Sixth Circuit decision represents "a conflicting approach to the interpretation of the Act" (Pet. 15). It is submitted that, in view of the denial of the petition in *AMP* and the conflicting views with respect to the instant case stated by petitioner in *AMP*, by the Government, and by this respondent, the differences of law and fact involved in the two cases should be clearly delineated for this Court as set forth below. We believe that such a delineation should lead this Court to grant a rehearing in the case at bar and to deny the Government's petition for a writ of certiorari.

1. The articles involved in the two cases are of entirely different kinds and the portions of the definitions of "drug" and "device" relating to the structure or function of the body (Sections 201(g)(1)(c) and 201(h)(2) of the Act), which are pertinent in *AMP*, are not applicable in any way in the Bacto-Unidisk case. It is clear from the testimony of the witnesses for both the Government and the respondent that the Bacto-Unidisk is used in the laboratory only and not in the "treatment of disease" within the meaning of Section 201(g)(1)(B), the only portion of the definition of "drug" which the Government seriously contends is applicable.* The disk,

* The original Government position that the disks were used in diagnosis and prevention was not pressed in the Court of Appeals. It is untenable.

therefore, satisfies no jurisdictional requirement of the definition of "drug" under Section 201(g)(1) of the Act. *AMP*, on the other hand, involves appliances which are used to ligate or tie off bleeding blood vessels during a surgical operation and which therefore affect the structure or function of the body within the meaning of Section 201(g)(1)(c) or 201(h)(2). The Government so noted in its Brief in Opposition in that case (p. 7). Moreover, nylon suture material is "recognized" in the United States Pharmacopeia and sensitivity disks are not.

No witness either for the Government or respondent would accede to the Government's suggestion that the Bacto-Unidisk was used in the treatment of disease (e.g., Dr. Truant, a witness for the Government, R. 74a-76a). Finding No. 8 (R. 146a-147a) states that "the information obtained from the sensitivity testing procedure outlined in Finding Number 7 is used by the physician as a guideline to treatment of the patient . . .". Since all witnesses agreed, there is no basis for disturbing this finding. It follows that no amount of argument can bring the Bacto-Unidisk into the scope of the definition of "drug" under the statute and that, therefore, there is no occasion for consideration of this case by this Court. It seems obvious that the issues in the Bacto-Unidisk case and those in *AMP* are entirely different.

2. The decision in *AMP* is not "principally relied on" by the United States in its petition in the Bacto-Unidisk case, as stated in the Petition for Rehearing in *AMP Incorporated* v. *Cohen* (p. 2).

On the contrary, both the petition of the Government in the Bacto-Unidisk case and the Reply Memorandum for the Petitioner therein seek primarily to persuade this Court to disregard the findings of fact and decisions below and to expand judicially the statutory definition of drug on the ground that, otherwise, harm may come to some patients by reason of the use of faulty sensitivity disks—despite the fact that no data showing even one in-

stance of such an occurrence could be produced at the trial by any Government witness.

The Government did state, in its petition, that *AMP* and other cases cited were in conflict with the Bacto-Unidisk decision because they rejected "common usage as determinative of what constitutes a drug" (p. 15).

The Bacto-Unidisk decisions did not, however, turn upon "common usage" as to what is a drug. The term "treatment of disease" in the definition of "drug" is a term of technical significance in medical science and was so treated by the Courts below and the parties, both of whom presented expert testimony as to its meaning. This was proper. *United States* v. *American Trucking Associations*, 310 U.S. 534, 543-544 (1940); *St. Luke's Hosp. Assoc. of Cleveland, Ohio* v. *United States*, 333 F. 2d 157 (6th Cir., 1964); Wigmore on Evidence, Vol. VII, Sections 1918, 1923, 1955, pp. 11, 21, 85. This testimony, and that relating to the meaning of the term "drug" did not deal with "common usage" but with the meaning of medical terms to medical doctors. Moreover, although it is not used in or on the body and is therefore not a drug in the *medical sense* (Finding No. 9, R. 147a), the Bacto-Unidisk would be a drug in the *statutory sense* if it purported to be or were represented to be for the treatment of disease (as the District Court found it was not, Finding No. 11, R. 148a), despite the fact that it could not be so classified on the basis of "common usage".

Obviously, therefore (a) the decisions below in *AMP* were not "principally relied on" by the Government in its Bacto-Unidisk petition and (b) to the extent there was reliance upon the *AMP* decisions it was misplaced.

It is submitted, therefore, that this case presents no material question of law or fact to this Court while *AMP* presents a substantial question of law. It is suggested further that the decision in *AMP* has no material relevance to the instant case because of the clear legal and factual differences herein set forth.

For these reasons and those stated in the Brief of Claimant Difco Laboratories, Inc. in Opposition we urge that rehearing be granted and that, thereupon, the petition for writ of certiorari to the United States Court of Appeals for the Sixth Circuit be denied.

Respectfully submitted,

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*Of Counsel:*

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## CERTIFICATE OF COUNSEL

I hereby certify that the foregoing petition for rehearing is presented in good faith and not for delay and is restricted to grounds specified in Rule 58 of the rules of this Court.

EDWARD BROWN WILLIAMS
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November 1968